UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

#54; JS-6(lc)

CIVIL MINUTES - GENERAL

Case No.	SACV 12-1647 PSG (FMOx)	Date	May 1, 2014
Title	Nathaniel L. Anderson v. Peregrine Pharmaceuticals, Inc., *et al.*		

Present:	The Honorable Philip S. Gutierrez, United States District Judge

Wendy K. Hernandez	Not Present	n/a
Deputy Clerk	Court Reporter	Tape No.

Attorneys Present for Plaintiff(s):	Attorneys Present for Defendant(s):
Not Present	Not Present

Proceedings: (In Chambers) Order GRANTING Motion to Dismiss

Before the Court is Defendants' motion to dismiss Plaintiff's Second Amended Complaint ("SAC"). Dkt. # 54. The Court finds this matter appropriate for decision without oral argument. *See* Fed. R. Civ. P. 78(b); L.R. 7-15. After considering the arguments in the moving, opposing, and reply papers, the Court GRANTS the motion to dismiss, without leave to amend.

I. Background

This is a putative class action securities case filed by Plaintiff James T. Fahey ("Plaintiff") against Defendants Peregrine Pharmaceuticals, Inc. ("Peregrine"), Steven W. King, Paul J. Lytle, Joseph S. Shan, and Robert L. Garnick (collectively, "Defendants"). Dkt. # 51. Plaintiff asserts causes of action for: (1) violation of § 10(b) of the Securities Exchange Act of 1934 ("Exchange Act") against all Defendants; and (2) violation of § 20(a) of the Exchange Act against the individual Defendants. *SAC* ¶¶ 298-313.

The parties and the Court are already familiar with the facts and core allegations in this case. *See* Dkts. # 42, 50. In short, Plaintiff alleges that Defendants made statements about Peregrine's Phase II clinical trial for bavituximab that were materially false and/or misleading in light of "major discrepancies" in the clinical trial data that Peregrine later disclosed. *SAC* ¶¶ 298-313. Those "major discrepancies" arose out of the fact that some of the trial patients who should have received bavituximab received a placebo, and vice versa. *See id.* ¶¶ 12-13, 71, 133, 210.

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On August 23, 2013, the Court dismissed Plaintiff's Consolidated Complaint for failure to adequately plead scienter. Dkt. # 42. Plaintiff subsequently filed a First Amended Complaint ("FAC"). Dkt. # 45. On November 22, 2014, the Court dismissed the FAC, holding that Plaintiff had again failed to adequately plead scienter. Dkt. # 50. Plaintiff filed the SAC on January 22, 2014. Dkt. # 51.

The significant differences between Plaintiff's FAC and SAC are few. Plaintiff has added some factual allegations from new confidential witnesses, and claims that Peregrine could have easily verified its Phase II clinical trial results after the trial was unblinded. *See, e.g.*, *SAC* ¶¶ 56-73, 90, 94, 98, 100, 102, 104, 106-107, 170, 188, 193. Plaintiff's other allegations related to scienter are effectively unchanged. Plaintiff continues to assert that Defendants were deliberately reckless because they failed to verify the data underlying the Phase II trial before publicly discussing its results, and/or because they failed to disclose that they had not verified the study data. *See id.* ¶¶ 13-14. Plaintiff also alleges that: (1) Peregrine touted the results of its Phase II trial to Abbvie, Inc. ("Abbvie"), a potential partner, but that Abbvie lost interest after Peregrine disclosed the problems with the trial, *id.* ¶¶ 135-145; (2) Clinical Supplies Management, Inc. ("CSM"), Peregrine's third-party research organization, has denied any liability related to the Phase II trial, *id.* ¶ 89; and (3) the individual Defendants were motivated to engage in wrongdoing to obtain year-end bonuses and stock options. *See id.* ¶¶ 275-284.

Defendants now move to dismiss the SAC. Dkt. # 54.

II. Legal Standard

A motion to dismiss under Rule 12(b)(6) tests whether the complaint "contain[s] sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *See Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). When deciding a Rule 12(b)(6) motion, the court must accept the facts pleaded in the complaint as true, and construe them in the light most favorable to the plaintiff. *Faulkner v. ADT Sec. Servs., Inc.*, 706 F.3d 1017, 1019 (9th Cir. 2013); *Cousins v. Lockyer*, 568 F.3d 1063, 1067-68 (9th Cir. 2009). The court, however, is not required to accept "legal conclusions . . . cast in the form of factual allegations." *W. Mining Council v. Watt*, 643 F.2d 618, 624 (9th Cir. 1981); *see Iqbal*, 556 U.S. at 678; *Twombly*, 550 U.S. at 555.

After accepting all non-conclusory allegations as true and drawing all reasonable inferences in favor of the plaintiff, the court must determine whether the complaint alleges a

plausible claim to relief. *See Iqbal*, 556 U.S. at 679-80. "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged. . . . The plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." *Id.* at 556 U.S. at 678 (citing *Twombly*, 550 U.S. at 556); *see Moss v. U.S. Secret Serv.*, 572 F.3d 962, 969 (9th Cir. 2009).

The Private Securities Litigation Reform Act of 1995 ("PSLRA") imposes a heightened pleading standard on federal securities fraud actions. 15 U.S.C. § 78u-4(b)(l), (2). "The PSLRA significantly altered pleading requirements in private securities fraud litigation by requiring that a complaint plead with particularity both falsity and scienter." *In re Vantive Corp. Sec. Litig.*, 283 F.3d 1079, 1084 (9th Cir. 2002) (citation omitted), *abrogation on other grounds recognized by South Ferry LP, No. 2 v. Killinger*, 542 F.3d 776, 784 (9th Cir. 2008). "The purpose of this heightened pleading requirement was generally to eliminate abusive securities litigation and particularly to put an end to the practice of pleading 'fraud by hindsight.'" *Id.* at 1084-85 (citation omitted).

With respect to scienter, the PSRLA requires plaintiffs to "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 USC § 78u-4(b)(2)(A). As with any Rule 12(b)(6) motion, when assessing a Rule 12(b)(6) motion to dismiss a §10(b) or § 20(a) action, courts must accept all factual allegations in the complaint as true. *See Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322 (2007). However, in the course of determining whether the allegations in the complaint give rise to a "strong inference" of scienter, "the court must take into account plausible opposing inferences." *Id.* at 323. After accounting for all plausible inferences both in favor of and against the plaintiff, and considering "all of the facts alleged, taken collectively," "the inference of scienter must be more than merely 'reasonable' or 'permissible'—it must be cogent and compelling," meaning that a complaint will survive "only if a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged." *Id.* at 322-24.

III. Discussion

A. Scienter

i. Recycled Arguments

UNITED STATES DISTRICT COURT
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A considerable portion of Plaintiff's opposition brief is dedicated to rehashing arguments the Court has already rejected. Most significantly, Plaintiff claims that Peregrine had a duty to verify its Phase II trial results before releasing information to the public, *Opp.* 3:1-4:2; and argues that the "core operations" doctrine is applicable here, *id* 10:13-13:22. The Court has already considered and rejected those arguments. *See Nov. 15, 2013 Order* at 4-5; *Aug. 13, 2013 Order* at 13-15. The Court has also previously addressed Plaintiff's claims regarding Abbvie, CSM, and individual Defendants' compensation. *See Nov. 15, 2013 Order* at 7; *Aug. 13, 2013 Order* at 16.

The proper way to dispute the Court's prior rulings is through a motion for reconsideration. Given that Plaintiff has not filed such a motion, the Court declines to revisit the analyses set out in its prior opinions.

ii. New Allegations

The crux of Plaintiff's new allegations is that Peregrine could have easily verified the results of the Phase II bavituximab trial, but failed to do so before announcing the trial's results. According to Plaintiff, when the trial was unblinded, Peregrine had access to the patient blood samples collected during the trial. *SAC* ¶ 12. Peregrine also had the ability to check whether any given blood sample contained bavituximab, using either of two different test methods. *See id.* ¶¶ 56-71. According to CW11 (a former Peregrine research associate) one scientist could have tested all 117 patient blood samples in approximately 18 hours using one of those methods, pharmacokinetic testing ("P-K testing"). *See id.* ¶¶ 59-65. According to CW3, CW9, and CW10 (respectively, a former Peregrine scientist, a former Peregrine research associate, and Peregrine's former manager of clinical operations) Peregrine also could have verified the Phase II results using a Human Anti-Chimeric Antibodies ("HACA") test. *See id.* ¶¶ 69-71, 129-130, 160, 165-166, 170, 185. Plaintiff further alleges that Peregrine had P-K test data it could have analyzed after the Phase II trial was unblinded, and that Peregrine conducted P-K tests after the trial was unblinded. *See id.* ¶¶ 168, 181-187.

These new allegations do not address the core issue in dispute. Contrary to Plaintiff's views, the issue here is not whether Defendants were faithful to the scientific method, *see Opp.* 1:15-1:20, or whether Defendants followed sound clinical practices, *see id.* 2:1-2:19. Nor is the issue whether Defendants were negligent, or even grossly negligent. The issue is whether Defendants acted with "deliberate recklessness." To establish "deliberate recklessness" in the securities context, the plaintiff must allege more than "simple, or even inexcusable negligence"—he must "plead a highly unreasonable omission, involving . . . an extreme

departure from the standards of ordinary care . . . which presents a danger of misleading buyers or sellers that is either *known* to the defendant or is so obvious that the actor *must have been aware* of it." *Zucco Partners, LLC v. Digimarc Corp.*, 552 F.3d 981, 991 (9th Cir. 2009) (quoting *In re Silicon Graphics Sec. Litig.*, 183 F.3d 970, 976 (9th Cir. 1999)) (internal quotation marks omitted and emphasis added). Put differently, "deliberate recklessness" is "conduct reflecting 'some degree of intentional or conscious misconduct.'" *Gebhart v. S.E.C.*, 595 F.3d 1034, 1041 n.10 (9th Cir. 2010) (quoting *Silicon Graphics*, 183 F.3d at 977). As the Court has explained, in the circumstances of this case, the crucial question is whether Defendants: (1) *knew* that there were "major discrepancies" in the Phase II clinical data or (2) were at least put *on notice* that there might be "major discrepancies." *See Nov. 15, 2013 Order* at 5-6; *Aug. 13, 2013 Order* at 12-12, 15, 17.

None of Plaintiff's new allegations are responsive to that inquiry. Even assuming that the confidential witnesses whose statements serve as the foundation for Plaintiff's claims are reliable, Plaintiff's allegations fall short of anything that would support a cogent and compelling inference of scienter.

CW1 and CW10 state that a central laboratory conducted (unspecified) tests on patient blood samples to determine that bavituximab was not making patients sicker, and reported results to Peregrine. *SAC* ¶¶ 122, 186. The witnesses do not indicate what those tests were, whether they could have revealed the problems in the Phase II trial, or whether any problems regarding the Phase II trial were reported to Defendants.

CW6, CW8, CW9, CW16, and CW19 state that clinical investigator sites ran (unspecified) tests on patient blood samples, reported the results of those tests to Peregrine, and sent patient blood samples to a central laboratory for further (unspecified) testing and reporting to Peregrine. *Id.* ¶¶ 91-92, 108, 112-113, 117-118, 161. CW7, CW13, and CW14 state that clinical investigators sent patient blood samples to a central laboratory for (unspecified) testing, *id.* ¶¶ 99, 100, 115; CW7 further states that the central laboratory reported test results to Peregrine. *Id.* ¶¶ 115. Again, the witnesses do not indicate what tests were conducted, whether those tests could have revealed the problems in the Phase II trial, or whether any problems regarding the Phase II trial were reported to Defendants.

CW4 states that clinical investigators provided Peregrine with patient data that included "the results of diagnostic tests such as blood tests[.]" *Id.* ¶ 151. The SAC is silent as to what blood tests were recorded in that data, whether those tests could have revealed the problems in

the Phase II trial, or whether any problems regarding the Phase II trial were reported to Defendants.

CW1, CW9, and CW11 state that Peregrine conducted P-K and HACA tests. *Id.* ¶¶ 123-124, 166-167, 195. CW3, CW17, and CW20 are more specific, and state that Peregrine conducted P-K and HACA tests on patient blood samples it received from investigator sites and the central laboratory. *Id.* ¶¶ 96, 105, 130. However, none of the witnesses state that Peregrine ran P-K or HACA tests in the time period between the unblinding of the Phase II trial and Defendants' public statements releasing the results of the Phase II trial. Moreover, none of the witnesses describe the extent of Peregrine's P-K/HACA testing on patient blood samples from the Phase II trial, making it impossible to gauge whether those tests would have brought the problems in the Phase II trial to light. None state that any Peregrine P-K or HACA tests actually revealed the problems with the Phase II trial.

These allegations only show that Peregrine could have uncovered the problems in the Phase II trial before going public. As the Court has explained, that is simply not enough to support an inference of scienter—much less a cogent and compelling inference of scienter.

In his opposition brief, Plaintiff cites allegations by two confidential witnesses that warrant further discussion. *See Opp.* 7:3-7:10. The Court addresses those witnesses separately.

CW10 was Peregrine's manager of clinical operations through July 2012. *See SAC* ¶ 170. In that capacity, CW10 planned for upcoming Phase III trials of the drug Cotara, and had some oversight responsibilities with respect to the Phase II bavituximab trial. *See id.* ¶ 172. According to the SAC, CW10 "described his job . . . as a 'high level' view of how to strategize and move traffic through each clinical trial. . . . CW10 was responsible for creating global flow charts for all clinical trials and overseeing the movement of drugs and data from various [contract research organizations], investigator sites and the central lab to keep it all moving and to get all clinical trials done in a timely and organized fashion." *Id.* ¶ 173.

According to CW10, P-K test data was sent to Defendant Shan in a spreadsheet "linked to a patient code using the ID assigned to each patient." *Id.* ¶ 181. A written report analyzing that data was also sent to Defendant Shan. *See id.* That report, among other things, "would look at how the concentration of bavituximab changed over time in the patient's blood[.]" *See id.* CW10 also states that "once the Phase II Trial was unblinded, Peregrine conducted P-K tests to analyze how bavituximab was working based on which patient received which dosage." *Id.* ¶ 183. CW10 opines that "the results of the P-K testing would be meaningful once the Phase II

trial results were unblinded and the patient codes were applied to each P-K test so that Peregrine could determine whether that patient had received bavituximab[.]" *Id.* ¶ 187.

CW10 notably does not offer any statements about the *results* of Peregrine's P-K testing, and does not indicate whether any reports sent to Defendants showed that patients who should have received bavituximab had received the placebo, or vice versa. CW10 also does not speak to the extent of Peregrine's P-K testing, or whether the P-K testing he/she describes was conducted before Defendants made the results of their Phase II trial public.

Further, it is not clear whether CW10 has personal knowledge of the contents of any reports or data sent to Defendants. To the contrary, key portions of the SAC based on CW10's statements are replete with qualifying phrases that suggest CW10 is engaging in speculation: CW10 discusses what written reports concerning P-K tests "*would* look at," states that a "P-K scientist *would have* produced a report synthesizing all test results," and indicates that "the results of the P-K testing *would be* meaningful once the Phase II trial results were unblinded[.]" *Id.* ¶¶ 182, 183, 187 (emphasis added). Even taken at face value, CW10's allegations do not establish that Defendants knew about or were on notice of the problems with the Phase II trial. When the apparent limits of CW10's personal knowledge are accounted for, his/her allegations are even more plainly insufficient to support the requisite cogent and compelling inference of scienter.

Plaintiff also cites, but does not discuss, an allegation that CW9 "believed that P-K testing was performed sometime after the study was unblinded in May of 2012[.]" *SAC* ¶ 168; *see Opp.* 7:10. CW9's *belief* is not tantamount to personal knowledge, particularly given that she does not explain the basis for her belief. Moreover, even if the Court found CW9's statement reliable—and it does not—her statement, like CW10's statements, does not indicate that Defendants knew about or were on notice of the problems with the Phase II trial. Notably, CW9 does not address the results of Peregrine's P-K testing, the extent of that testing, whether the P-K testing she believes took place was conducted before Defendants made the results of their Phase II trial public, or whether the results of the purported tests were passed on to Defendants.

In summary, Plaintiff has not adequately pleaded that any Defendant acted with "deliberate recklessness." As a result, Plaintiff's § 10(b) and § 20(a) claims fail, and are DISMISSED.

B. Leave to Amend

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Plaintiff has requested leave to amend in the event the Court finds the SAC inadequate. *Opp.* 25:21-25:22.

In determining whether leave to amend is warranted, the Court considers: (1) a party's bad faith; (2) undue delay; (3) prejudice to the opposing party; (4) futility; and (5) whether the plaintiff has previously amended his complaint. *See Sisseton-Wahpeton Sioux Tribe v. United States*, 90 F.3d 351, 355 (9th Cir. 1996). When a plaintiff has previously been granted leave to amend and has subsequently failed to add the necessary particularity to his claims, "[t]he district court's discretion to deny leave to amend is particularly broad." *Zucco Partners*, 552 F.3d at 1007 (internal quotations and citations omitted) (alteration in original).

The Court has already allowed Plaintiff to amend his pleadings twice. Dkts. # 42, 50. As a result, the Court's discretion to deny leave to amend is broad. *See Zucco Partners*, 552 F.3d at 1007.

This case has been in litigation since September 2012. Dkt. # 1. Granting Plaintiff a fourth chance to plead his claims would mean that Plaintiff would be filing a complaint over a year and a half after he initiated this lawsuit. Moreover, Plaintiff's repeated attempts to re-litigate issues that have already been decided, together with Plaintiff's failure to specify what amendments he might make if granted leave to amend, strongly suggest that granting leave to amend would be futile. Under the circumstances, the Court finds it appropriate to deny leave to amend.

IV. Conclusion

For the reasons above, the Court GRANTS Defendants' motion to dismiss, without leave to amend.

IT IS SO ORDERED.